UNITED STATES DISTRICT COURT
DISTRICT OF SOUTH CAROLINA
FLORENCE DIVISION

Dillon County, South Carolina,	**C.A. No. _____**
Plaintiff,	
vs.	
Amerisourcebergen Drug Corporation, Cardinal Health, 110, LLC, and McKesson Corporation,	**COMPLAINT (JURY TRIAL DEMANDED)**
Defendants.	

The Plaintiff, DILLON COUNTY, SOUTH CAROLINA, complaining of the Defendants herein, respectfully alleges as follows:

I. PARTIES.

A. PLAINTIFF, DILLON COUNTY, SOUTH CAROLINA.

1. Plaintiff, DILLON COUNTY, SOUTH CAROLINA, ("Plaintiff" or "Dillon County") is a governmental entity established under the laws and constitution of the State of South Carolina. Dillon County is a body politic and corporate empowered to exercise its powers to preserve health, peace, and order for its citizens. *S.C. Code Ann.* § 4-9-25.

2. Pursuant to these powers, Dillon County has standing to bring this action. *Id.*

B. DEFENDANTS – WHOLESALE DISTRIBUTORS.

3. Defendant, MCKESSON CORPORATION, is a foreign corporation, organized and existing pursuant to the laws of the State of Delaware, and authorized to do business and doing business in the State of South Carolina. It is registered with the South Carolina Secretary

of State as a Delaware corporation which may be served through its registered agent for service of process, Corporation Service Company, 1703 Laurel Street, Columbia, South Carolina 29201. McKesson Corporation has its principal place of business located in San Francisco, California. McKesson is the largest pharmaceutical distributor in North America. It delivers more than one-third of all pharmaceuticals used in North America. Among its many business interests, McKesson distributes pharmaceuticals to retail pharmacy operations as well as institutional providers such as hospitals and county health departments.

4. Defendant, AMERISOURCEBERGEN DRUG CORPORATION, is a corporation, organized and existing pursuant to the laws of the State of Delaware, and authorized to do business and doing business in the State of South Carolina. It is registered with the South Carolina Secretary of State as a Delaware corporation which may be served through its registered agent for service of process, CT Corporation System, 2 Office Park Court, Suite 103, Columbia, South Carolina. Amerisourcebergen Drug Corporation's principal place of business is located in Chesterbrook, Pennsylvania. Amerisourcebergen is the second largest pharmaceutical distributor in North America. It delivers around one-third of all pharmaceuticals used in North America. Like McKesson, Amerisourcebergen distributes pharmaceuticals to retail pharmacy operations, as well as institutional providers such as hospitals and county health departments.

5. Defendant, CARDINAL HEALTH 110, LLC is a corporation, organized and existing pursuant to the laws of the State of Ohio, and authorized to do business and doing business in the State of South Carolina. Cardinal's principal place of business is located in Dublin, Ohio. Like McKesson, Cardinal Health distributes pharmaceuticals to retail pharmacy operations, as well as institutional providers like hospitals and county health departments.

Cardinal is the third largest pharmaceutical distributor in North America.

6. Defendants AMERICANBERGEN, MCKESSON and CARDINAL are wholesale distributors as that phrase is defined by § 40-43-30 (54) *S.C. Code Ann*. Together, they account for 85% to 90% of the wholesale drug distribution in the United States. They play a principle role in the chain of distribution of prescription opioids, including hydrocodone and oxycodone. These Defendants are hereinafter collectively referred to as "Defendant Wholesale Distributors."

7. Data which reveal the identity of other potential wrongdoers is hidden from public view in the confidential database of the U.S. Department of Justice, Drug Enforcement Administration ("DEA"), the Automation of Reports and Confidential Orders System ["ARCOS"]. *Madel v. USDOJ*, 784 F.3d 448 (8th Cir. 2015). Neither the DEA[1] nor the Defendant Wholesale Distributors[2] will voluntarily disclose the data necessary to identify with specificity the transactions which form the basis for the claims asserted herein. Consequently, Plaintiff has named the three (3) wholesale distributors which dominate the market share for the distribution of prescription opioids. The "Big 3" are Fortune 500 corporations listed on the New York Stock Exchange whose principal business is the nationwide wholesale distribution of

---

[1] *See* Declaration of Katherine L. Myrick, Chief, Freedom of Information (FOI), Records Management Section, DEA, *Madel v. USDOJ*, Case 0:13-cv-02832-PAM-FLN, (Document 23) (Filed 02/06/14) attached hereto as Exhibit 1 (noting that ARCOS data is "kept confidential by the DEA" and the "release of the information would result in substantial competitive harm to [Cardinal Health, AmerisourceBergen and McKesson Corp.]"

[2] *See* Declaration of Tina Lantz, Cardinal Health VP of Sales Operation, *Madel v. USDOJ,* Case No. 0-13–cv-02832-PAM-FLN, (Document 93 (Filed 11/02/16), attached hereto as Exhibit 2 ("Cardinal Health does not customarily release any of the information identified by the DEA notice letter to the public, nor is the information publicly available. Cardinal Health relies on DEA to protect its confidential business information reported to the Agency.").

prescription drugs. *Fed. Trade Comm'n v. Cardinal Health*, Inc., 12 F.Supp. 2d 34, 37 (D.D.C. 1998). Each has been investigated and/or fined by the DEA for the failure to report suspicious prescription drug orders. Plaintiff is informed and believes that each has engaged in unlawful conduct which resulted and continues to result in the diversion of prescription opioids into the Dillon County community.

II. JURISDICTION AND VENUE.

8. The Plaintiff is a political subdivision of the State of South Carolina, but not its alter ego. As such, Dillon County is a resident and citizen of the State of South Carolina for diversity jurisdiction purposes. Defendants are foreign corporations with their principal places of business in states other than the state of South Carolina. As such, jurisdiction is proper with this Court based upon diversity jurisdiction pursuant to 28 U.S.C. § 1332.

9. Venue is proper in this judicial district and the Florence Division pursuant to Local Rule 3.01 D.S.C. because the events giving rise to this claim occurred in this District within the Florence Division.

10. Plaintiff has suffered damages which exceed $75,000.00, exclusive of interest and costs.

III. FACTUAL BACKGROUND.

11. Prescription opioids, which include well-known brand-name drugs like OxyContin and Percocet, as well as generic versions of oxycodone and hydrocodone, are narcotics. They are derived from or possess properties similar to opium and heroin, and thus, they are regulated as controlled substances.

12. Like heroin, prescription opioids work by binding to receptors on the spinal cord

and in the brain, dampening the perception of pain. Opioids also can create a euphoric high, which makes them highly addictive.

13. At higher doses, opioids can slow the user's breathing, causing respiratory depression and, ultimately, death. It is well-known and well-documented that opioids can be lethal in high doses.

14. Opioids are effective treatments for short-term post-surgical and trauma-related pain and for palliative (end-of-life) care. However, because opioids are highly addictive, they are subject to abuse, particularly when used for chronic non-cancer pain.

15. As pharmaceutical distributors, Defendant Wholesale Distributors have known for many years that with prolonged use, the effectiveness of opioids wanes, requiring increases in doses and markedly increasing the risk of significant side effects and addiction.

16. Defendant Wholesale Distributors also know that controlled studies of the safety and efficacy of opioids have been limited to short-term use, mostly in managed settings, where the risk of addiction and other adverse outcomes is much less significant.

17. The U.S. Food and Drug Administration ["FDA"] has expressly recognized that there have been no long-term studies demonstrating the safety and efficacy of opioids for long-term use, stating it was "not aware of adequate and well-controlled studies of opioid use longer than 12 weeks."

18. Opioid painkillers are widely diverted and improperly used. The widespread misuse of these drugs has resulted in a national crisis of rising opioid overdose deaths and

addictions.[3] The crisis is "directly related to the increasingly widespread misuse of powerful opioid pain medications."[4] There is "a parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes."[5]

19. Opioids – once considered niche drugs - are now the most prescribed class of drugs in this country, exceeding blood pressure, cholesterol, or anti-anxiety drugs. While Americans represent only 4.6% of the world's population, they consume 80% of the opioids supplied around the world, and 99% of the global hydrocodone supply. Together, opioids generated $8 billion in revenue for drug companies in 2012, a number that almost doubled to more than $15 billion in 2016.

20. Moreover, opioid abuse has not displaced heroin, but rather has triggered a resurgence in its use. The Centers for Disease Control ("CDC") has identified addiction to prescription pain medications as the strongest risk factor for heroin addiction. People who are addicted to prescription opioids are forty times more likely to be addicted to heroin.[6]

21. Heroin is pharmacologically similar to prescription opioids. Roughly 80% of

---

[3] *See* Nora D. Volkow, M.D., and A. Thomas McLellan, Ph.D., *Opioid Abuse in Chronic Pain – Misconceptions and Mitigation Strategies*, NEW ENG. J. MED., 374; 1253-63 (March 31, 2016).

[4] *See* Special Report, FDA Commissioner Robert M. Califf, M.D., *A Proactive Response to Prescription Opioid Abuse*, NEW ENG. J. MED., 374; 1480-85 (April 14, 2016).

[5] *See* Richard C. Dart, M.D., Ph.D., et al. *Trends in Opioid Analgesic Abuse and Mortality in the United States*, NEW ENGL. J. MED., 372;241-248, 245 (January 15, 2015).

[6] *See* CDC Vital Signs Fact Sheet, *Today's Heroin Epidemic*, U. S. Department of Health and Human Resources, Centers for Disease Control and Prevention (July 2015).

heroin users report having previously used prescription opioids before they initiated heroin use.[7] Statewide, overdoses in South Carolina involving heroin increased by 57% from 2014 to 2015.

22. According to the CDC, the percentage of heroin users who also use opioids rose from 20.7% between 2002 and 2004 to 45.2% between 2011 and 2013. Heroin produces a very similar high to prescription opioids, but is often cheaper. While a single opioid pill may cost $10-$15 on the street, users can obtain a bag of heroin, with multiple highs, for the same price. The powerful pull that causes a previously law-abiding, middle-aged soccer mom, who was started on prescription opioids for a back injury, to turn to buying, snorting, or injecting heroin, is a dark truth of opioid abuse and addiction upon which this Complaint seeks to shine a light.

23. Dr. Robert DuPont, former director of the National Institute on Drug Abuse and a former White House drug czar, notes that opioids are more destructive than crack cocaine:

> [Opioid abuse] is building more slowly, but it's much larger. And the potential[] for death, in particular, [is] way beyond anything we saw then.... [F]or pain medicine, a one-day dose can be sold on the black market for $100. And a single dose can [be] lethal to a non-patient. There is no other medicine that has those characteristics. And if you think about that combination and the millions of people who are using these medicines, you get some idea of the exposure of society to the prescription drug problem.

24. Over the past two decades, the DEA has battled a steep increase in prescription opioid abuse – a problem that the DEA has called an "epidemic."

25. The U.S. Department of Health and Human Services ["HHS"] has described the

---

[7] *See* Wilson M. Compton, M.D., M.P.E., et al., *Relationship between Non-Medical Prescription Opioid Use and Heroin Use*, NEW ENGL. J. MED., 374;154-63 (January 14, 2016).

rising abuse of prescription opioids as "a serious and challenging" public health issue.[8] Since 1999, the number of deaths from prescription painkillers in the United States has more than quadrupled.[9] From 2000 to 2015 more than half a million people died from drug overdoses.[10] Prescription opioids now kill an average of 91 Americans per day.[11]

26. The outcomes in South Carolina are equally catastrophic – and getting worse. Over the past 5 years, more than 3,000 South Carolinians have died from overdoses of prescription opioids.

27. Cities and counties are on the front lines fighting this scourge where the misuse, abuse, and overdose of prescription pain pills has destroyed lives and ruined local economies.

A. Defendants Have Affirmative Duties to Maintain Effective Controls against Diversion of these Dangerous, Addictive Drugs for Non-Legitimate, Non-Medical Purposes.

28. Since the 1970s, opioids have been regulated both nationally and in South Carolina under the Controlled Substances Act, 21 U.S.C. § 801 *et seq*., and the South Carolina Controlled Substances Act, *S.C. Code Ann.*, § 44-53-10 *et seq.*

29. Accordingly, opioids such as hydrocodone and oxycodone are not sold directly to physicians or pharmacies for ultimate dispensing. They are listed as controlled substances so that

---

[8] Dep't of Health & Human Servs., *Opioid Abuse in the U.S. and HHS Actions to Address Opioid-Drug Related Overdoses and Deaths* (2015).

[9] Centers for Disease Control and Prevention, *Opioid Overdose: Understanding the Epidemic*, https://www.cdc.gov/drugoverdose/ epidemic/index.html.

[10] U.S. Dept. of Health & Human Servs., *About the Epidemic*, https://www.cdc.gov/drugoverdose/epidemic/index.html. *See, also, Masters Pharm., Inc. v. DEA*, 861 F.3d 206, 211, 2017 U.S. App. LEXIS 11666, *2, 2017 WL 2818639 (D.C. Cir. June 30, 2017).

[11] *Id.*

they can be monitored and their sale restricted.

30. The distribution system for controlled drugs was set up by Congress in the 1970s. This sophisticated system is a "closed" chain of distribution specifically designed to prevent the diversion of legally produced controlled substances into the illicit market.[12] The system relies heavily on the honesty, integrity and accountability of the wholesale pharmaceutical distributors.

31. The role of the wholesale distributor under this closed system of distribution is not simply one of shelf stocker, freight forwarder, or simple shipper. Wholesale distributors are required to monitor, identify, halt and report "suspicious orders" of controlled substances.[13]

32. Defendant Wholesale Distributors are "one of the key components of the distribution chain. If the closed system is to function properly "... distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as ... the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people."[14]

33. Consequently, the critical duty to ensure that controlled drugs do not end up in the wrong hands is borne by wholesale distributors. In exchange for promising to honor these

---

[12] *Gonzales v. Raich*, 545 U.S. 1, 12-14 (2005); 21 U.S.C. § 801(2); 21 U.S.C. §§ 821-824, 827, 880; H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. 4566, 4572 (Sept. 10, 1970).

[13] 21 C.F.R. § 1301.74; *Master Pharm, Inc. v. DEA*, *supra*.

[14] *See* DEA letter signed by from Joseph T. Rannazzisi, Deputy Assis, Admin., Office of Diversion Control, to Cardinal Health (September 27, 2006), attached as Exhibit 3 ("This letter is being sent to every commercial entity in the United States registered with the Drug Enforcement Agency (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces.")**.**

obligations, each of the wholesale distributors is licensed and/or registered by the DEA and ultimately receives compensation in the form of millions of dollars each year for shipping large volumes of drugs, well beyond what a reasonable company would expect.

34. Healthcare Distribution Alliance (HDA), formerly known as the Healthcare Distribution Management Association (HDMA), is the leading trade group of distributors.[15] According to HDA, "[h]ealthcare distribution has never been just about delivery. It's about getting the right medicines to the right patients at the right time, safely and efficiently."[16]

35. The website for HDA explains that "[w]hile distributors do not prescribe or dispense drugs directly to patients, they do share a common goal with physicians, manufacturers, pharmacists, law enforcement officials, and policymakers: to ensure a safe supply of medicines. Among other safeguards, distributors are dedicated to keeping prescription painkillers out of the hands of people who may use them for purposes other than those for which they are intended."[17]

36. According to their website, members of HDA, including the Defendant Wholesale Distributors named herein, are supposed to man the front lines in addressing the threat of prescription opioids ending up in the wrong hands. Their multilayered approach, per the website, includes the following, at least in theory:

- Our members register with the DEA and follow rigorous statutory and regulatory requirements for the storage, handling and distribution of controlled substances. These sophisticated security systems and processes

---

[15] The HDA is a national, not-for-profit trade association that represents the nation's primary, full-service healthcare distributors whose membership includes, among other: AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and McKesson Corporation.

[16] *See* https://www.hda.org/about/role-of-distributors.

[17] *See* http://www.hdma.net/issues/prescription-drug-abuse-and-diversion.

help safeguard the supply chain.

- Pharmaceutical distributors coordinate with a range of supply chain partners, as well as federal and state regulatory agencies, to help prevent the diversion of prescription drugs.

- We work with supply chain stakeholders, including pharmaceutical manufacturers, hospitals, retail pharmacies and other healthcare providers, to share information and develop strategies to identify and help prevent abuse and diversion.

- We work collaboratively with law enforcement and regulators to combat bad actors who attempt to breach the security of the legitimate supply chain, coordinating with law enforcement and regulators to offer information technology, security and logistics expertise that helps locate and prosecute individuals who attempt to misuse and divert prescription drugs from the legitimate supply chain.

- We take steps to "know our customers," including actively assessing and reviewing purchases from pharmacies and healthcare providers that order controlled substances to monitor and report to the DEA if a customer's controlled substances volume or pattern of ordering might signal inappropriate use of the product. If inappropriate use is suspected, distributors work proactively with DEA, local law enforcement and others to help in the investigation of potential diversion cases.

- We provide the DEA with additional data and reports to aid their efforts to seek out criminal behavior. Distributors communicate about any handling of selected controlled substances to the DEA's reporting system, Automation of Reports and Consolidated Orders System (ARCOS). This system monitors the flow of DEA controlled substances from their point of manufacture through commercial distribution channels to the point of sale at the dispensing/retail level.

37. McKesson has publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders," and has claimed that it is "deeply passionate about curbing the opioid epidemic in our country."[18]

[18] Scott Higham et al., *Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb Opioid Abuse*, Washington Post, December 22, 2016, available at https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-

38. In its 2013 annual report to shareholders, McKesson boasted of its "award winning Acumax® Plus technology [which] provides real time product availability, Mobile Manager which integrates Acumax® Plus to give customers complete ordering and inventory control and McKesson Connect, an internet based ordering system that provides item lookup and real-time inventory availability as well as ordering, purchasing, reconciliations, and account management functionality." The 2013 Annual Report concludes that "together, these features help ensure customers have the right products at the right time."

39. McKesson further proudly pronounced that it follows lean Six Sigma methodology which, according to the 2013 annual report, is "an analytical approach that emphasizes setting high-quality objectives, collecting data and analyzing the results to a fine degree in order to improve processes, reduce costs and minimize errors."

40. Like McKesson, Cardinal also employs lean Six Sigma methods in its operations. Cardinal Health began its lean Six Sigma journey in 2007, as part of an initiative to "drive collaboration in the health care supply chain, with the goal of achieving zero errors, zero waste and zero lost revenue."[19] According to a 2012 article, "the company uses predictive analytics, fed by transactional information provided by suppliers, to increase the speed of communication from the manufacturer to the end customer."[20] Cardinal's Vice President of Inventory Management, Andy Keller, further noted that "[w]e're a critical link in the supply chain because we talk to both

---

pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html?utm_term=.68a58d17478e.

[19] *See* http://www.industryweek.com/supply-chain/supply-chain-and-logistics-lean-six-sigma-keeps-cardinals-supply-chain-healthy.

[20] *Id.*

suppliers and health care providers."[21]

41. Cardinal has publicly touted its use of "advanced analytics" to monitor its supply chain, and has assured the public it was conducting its business "as effective[ly] and efficient[ly] as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."[22]

42. In spending millions of dollars on systems and technology to collect and analyze robust data and utilizing lean Six Sigma methodology, Defendant Wholesale Distributors certainly would have assessed the extent of their lethal overshipments to places like Dillon County, South Carolina. Rather than taking steps to protect the end user from the dangerous and addictive drugs, Defendant Wholesale Distributors instead chose to keep the supply lines open. Given the sales volumes and the Wholesale Distributors' history of violations, their public assurances either were false, or they intentionally ignored the data from their monitoring programs.

43. The incontrovertible fact is that Defendant Wholesale Distributors have shipped millions of doses of highly addictive controlled opioid drugs into relatively small locales, many of which, according to their own policies as well as state laws, should have been stopped and/or investigated as suspicious orders, but were not.

44. The Plaintiff is informed and believes that each Defendant engaged in flooding the market, including Dillon County, South Carolina, with extraordinary and excessive doses of

---

[21] *Id.*

[22] Lenny Bernstein et al., "*How drugs intended for patients ended up in the hands of illegal users; 'No one was doing their job*,'" Washington Post, October 22, 2016, available at https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html?utm_term=.7744e85035bdc.

dangerous and addictive controlled opioid drugs and failed to comply with federal and state law. Such unlawful conduct resulted in the foreseeable, widespread diversion of prescription opioids into the illicit market, creating a serious public health and safety crisis.

1. Defendants were at all relevant times on notice of their duties *vis-a-vis* suspicious opioid orders.

45. Different entities supervise the discrete links in the chain that separate a consumer from a controlled substance. Statutes and regulations carefully define each participant's role and responsibilities.

46. "Suspicious orders" are defined to include orders of an unusual size, orders of unusual frequency, or orders deviating substantially from a normal pattern. *See* 21 C.F.R. 1301.74(b); S.C. ADC 61-4.143. These criteria are disjunctive and are not all-inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a wholesale distributor need not wait for a normal pattern to develop over time before determining whether a particular order is suspicious and a deviation from the norm. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger the wholesale distributor's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the entirety of the wholesale distributors' customer base, and the patterns throughout the relevant segment of the wholesale distributor industry.

47. On September 27, 2006, the DEA sent to each of the Defendant Wholesale Distributors a letter warning that it would use its authority to revoke and suspend registrations

when appropriate. The letter expressly stated that a distributor, in addition to reporting suspicious orders, had a "statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels."[23] The letter also instructed that "distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes."[24] The DEA warned that "even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm."[25]

48. The DEA sent a second letter to each of the Defendant Wholesale Distributors on December 27, 2007.[26] This letter reminded the Defendant Wholesale Distributors of their statutory and regulatory duties to "maintain effective controls against diversion" and to "design and operate a system to disclose to the registrant suspicious orders of controlled substances."[27] The letter further explained:

> The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders when discovered by the registrant. Filing a monthly report of completed transactions (e.g., "excessive purchase report" or "high unity purchases") does not meet the regulatory requirement to report suspicious orders. Registrants are reminded that their responsibility does not end merely with the

---

[23] *See, e.g.,* DEA letter signed by from Joseph T. Rannazzisi, Deputy Assis, Admin., Office of Diversion Control, to Cardinal Health (Sept. 27, 2006), at page 2 (discussing 21 U.S.C. § 823(e)). A copy of letter is attached as Exhibit 3.

[24] *Id*, at page 1.

[25] *Id*, at page 2.

[26] *See, e.g.,* DEA letter signed by Letter from Joseph T. Rannazzisi, Deputy Assis. Admin., Office of Diversion Control, to Cardinal Health (Dec. 27, 2007). A copy of letter is attached hereto as Exhibit 4.

[27] *Id*.

filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an Order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.

The regulation specifically states that suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a registrant need not wait for a "normal pattern" to develop over time before determining whether a particular order is suspicious. The size of an order alone, whether or not it deviates from a normal pattern, is enough to trigger the registrant's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the registrant's customer base and the patterns throughout the segment of the regulated industry.

Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders. For example, a system that identifies orders as suspicious only if the total amount of a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient. This system fails to identify orders placed by a pharmacy if the pharmacy placed unusually large orders from the beginning of its relationship with the distributor. Also, this system would not identify orders as suspicious if the orders were solely for one highly abused controlled substance if the orders never grew substantially. Nevertheless, ordering one highly abused controlled substance and little or nothing else deviates from the normal pattern of what pharmacies generally order.

When reporting an order as suspicious, registrants must be clear in their communication with DEA that the registrant is actually characterizing an order as suspicious. Daily, weekly, or monthly reports submitted by registrant indicating "excessive purchases" do not comply with the requirement to report suspicious orders, even if the registrant calls such reports "suspicious order reports."

Lastly, registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion. Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 USC 823 and 824,

> and may result in the revocation of the registrant's DEA Certificate of Registration.[28]

Finally, the DEA letter referenced the final order issued in *Southwood Pharmaceuticals, Inc.*, 72 FR 36487 (2007) [2007 WL 1886484], which discussed the obligation to report suspicious orders and included some of the "criteria to use when determining whether an order is suspicious."[29]

49. Moreover, even trade groups have affirmatively enumerated the extensive statutory and regulatory responsibilities of Defendant Wholesale Distributors in advocating on their behalf of Defendants in Court filings:[30]

- HDMA and NACDS members not only have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs, but undertake such efforts as responsible members of society.
- DEA regulations that have been in place for more than 40 years require distributors to report suspicious orders of controlled substances to DEA based on information readily available to them (e.g., a pharmacy's placement of unusually frequent or large orders).
- Distributors take seriously their duty to report suspicious orders, utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information that is available to them in the ordering process.
- A particular order or series of orders can raise red flags because of its unusual size, frequency, or departure from typical patterns with a given pharmacy.
- Distributors also monitor for and report abnormal behavior by pharmacies placing orders, such as refusing to provide business contact information or

---

[28] *Id.*

[29] *Id.*

[30] *See* Amicus Curiae Brief of HDMA (now HDA) in Support of Appellant Cardinal Health, Inc., *Cardinal Health, Inc. v. United States Dept. Justice*, 2012 WL 1637016, *2 (C.A.D.C.) (May 9, 2012). A copy is attached at Exhibit 5.

insisting on paying in cash.

50. Defendant Wholesale Distributors knew they were required to monitor, detect, report, and refuse to fill suspicious orders. The HDMA industry compliance guidelines explain that distributors are "[a]t the center of a sophisticated supply chain" and therefore "are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers."[31] The guidelines set forth recommended steps in the "due diligence" process, and note in particular: "If an order meets or exceeds a distributor's threshold, as defined in the distributor's monitoring system, or is otherwise characterized by the distributor as an order of interest, the distributor should not ship to the customer, in fulfillment of that order, any units of the specific drug code product as to which the order met or exceeded a threshold or as to which the order was otherwise characterized as an order of interest."[32]

2. At all relevant times, each Defendant was acting under a duty to guard against the diversion of prescription opioids for non-medical purposes.

51. Each of the Defendant Wholesale Distributors sold prescription opioids, including hydrocodone and/or oxycodone, to retailers in Dillon County, South Carolina and/or to retailers through which Defendant knew drugs were likely to be delivered and/or diverted into Dillon County.

52. Defendant Wholesale Distributors owed a duty to detect suspicious orders of prescription opioids originating from Dillon County, South Carolina and/or orders of prescription opioids which Defendants knew or should have known were likely to be delivered and/or

[31] *See* HDMA Industry Compliance Guidelines. A copy is attached hereto as Exhibit 6.

[32] *Id.*

diverted into Dillon County.

53. Defendant Wholesale Distributors owed a duty to investigate suspicious orders of prescription opioids originating from Dillon County, South Carolina and/or orders of prescription opioids which Defendants knew or should have known were likely to be delivered and/or diverted into Dillon County.

54. Defendant Wholesale Distributors owed a duty to refuse suspicious orders of prescription opioids originating from Dillon County, South Carolina and/or orders of prescription opioids which Defendants knew or should have known were likely to be delivered and/or diverted into Dillon County.

55. Defendant Wholesale Distributors owed a duty to report suspicious orders of prescription opioids originating from Dillon County, South Carolina and/or orders of prescription opioids which Defendants knew or should have known were likely to be delivered and/or diverted into Dillon County.

56. Defendant Wholesale Distributors owed a duty to maintain effective controls against the diversion of prescription opioids into illicit markets in Dillon County, South Carolina.

57. The diversion of prescription opioids for nonmedical purposes is the direct, proximate and foreseeable harm resulting from a breach of these duties of Defendant Wholesale Distributors.

58. The direct, proximate and foreseeable consequence resulting from the diversion of prescription opioids for nonmedical purposes is abuse, addiction, morbidity and mortality in Dillon County, South Carolina, and the damages stemming therefrom.

B. Defendants Breached Their Duties Deliberately, Knowingly, and for Profit.

1. Defendant Wholesale Distributors' compliance with their legal duties is critical, particularly considering the sharp increase in opioid prescriptions.

59. Because wholesale distributors handle such large volumes of controlled substances, and are the first major line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market, it is incumbent upon distributors to maintain effective controls to prevent diversion of controlled substances. Should a distributor deviate from these critical checks and balances, the closed system collapses.[33]

60. The United States consumes opioid pain relievers at a greater rate than any other nation. Dillon County, South Carolina has an opioid prescription rate of 127.2 per 100 persons, one of the highest in the state of South Carolina.[34] According to a recent study by Blue Cross and Blue Shield (BCBS) twenty-one to twenty-three (21-23%) percent of its South Carolina commercially-insured members filled at least one opioid prescription in 2015.[35]

61. The sheer volume of prescription opioids distributed to pharmacies in Dillon County, South Carolina is patently excessive for the medical needs of the community and facially

---

[33] *See* Declaration of Joseph Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Agency, United States Department of Justice, ¶10, *Cardinal Health, Inc. v. Holder*, No. 1:12-cv-00185-RBW. A copy of the declaration is attached hereto as Exhibit 7.

[34] *See* https://www.cdc.gov/drugoverdose/maps/rxcounty2016.html;https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html. *See also*, Leonard J. Paulozzi, M.D., et al., *Vital Signs: Variation Among States in Prescribing of Opioid Pain Relievers and Benzodiazepines - United States*, 2012, Morbidity and Mortality Weekly Report, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services (July 4, 2014).

[35] BCBS, America's Opioid Epidemic and Its Effect on the Nation's Commercially Insured Population (June 29, 2017). A copy is attached hereto as Exhibit 8.

suspicious. Certain red flags are so obvious that no one who engages in the legitimate distribution of controlled substances can reasonably claim ignorance of them.[36]

2. Defendants breached their duties.

62. The Plaintiff is informed and believes that the Defendant Wholesale Distributors failed to report to the DEA, the South Carolina Bureau of Drug Control and/or Board of Pharmacy "suspicious orders" originating from Dillon County, South Carolina and/or orders of prescription opioids which Defendants knew or should have known were likely to be delivered and/or diverted into Dillon County.

63. Defendant Wholesale Distributors unlawfully filled suspicious orders of unusual size, orders deviating substantially from a normal pattern, and/or orders of unusual frequency in Dillon County, South Carolina and/or orders which Defendants knew or should have known were likely to be delivered and/or diverted into Dillon County.

64. Each Defendant Wholesale Distributor breached its duty to maintain effective controls against diversion of prescription opioids from legitimate medical, scientific, and industrial channels.

65. Each Defendant Wholesale Distributor breached its duty to design and operate a system to reliably alert it to suspicious orders of controlled substances. It failed to inform the South Carolina Bureau of Drug Control and DEA of suspicious orders for drugs when discovered. *See* S.C. ADC 61-4.404.

---

[36] *See Master Pharmaceuticals, Inc.*; Decision and Order, 80 FR 55418-01, 55482 (Sept. 15, 2015) (citing *Holiday CVS, L.L.C. d/b/a CVS Pharmacy* Nos. 219 and 5195, 77 FR 62,316, 62,322 (2012)); *Master Pharmaceuticals, Inc. v. Drug Enforcement Administration*, No. 15-11355 (D.C. Cir. June 30, 2017).

66. Each Defendant Wholesale Distributor breached its duty to provide effective controls and procedures to guard against theft and diversion of controlled substances in violation of federal law and South Carolina law. *See, e.g.,* C.F.R. § 1301.74(b); S.C. ADC 61-4.404.

67. Each Defendant Wholesale Distributor breached its duty to monitor, detect, investigate, refuse to fill, and report suspicious orders of prescription opioids originating from Dillon County, South Carolina and/or which Defendants knew or should have known were likely to be delivered and/or diverted into Dillon County.

68. Each Defendant Wholesale Distributor breached its duty to exercise due diligence to avoid filling suspicious orders that might be diverted from legitimate medical, scientific and industrial channels. *Cardinal Health, Inc. v. Holder*, 846 F. Supp.2d 203, 206 (D.D.C. 2012).

69. Defendant Wholesale Distributors' violations of mandatory safety statutes and regulations enacted for the safety of the public is negligence *per se*.

3. Defendants' serial violations of the law.

70. As a result of the decade-long refusal by the Defendant Wholesale Distributors to abide by federal law, the DEA has repeatedly taken administrative action to force compliance. The United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Division, reported that the DEA issued final decisions in 178 registrant actions between 2008 and 2012. The Office of Administrative Law Judges issued a recommended decision in a total of 117 registrant actions before the DEA issued its final decision, including 76 actions involving orders to show cause and 41 actions involving immediate suspension orders.[37]

[37] *The Drug Enforcement Administration's Adjudication of Registrant Actions,* United States Department of Justice, Office of the Inspector General, Evaluation and Inspection Divisions, 102914-003 (May 2014).https://webcache.googleusercontent.com/search?q=cache:

These actions include the following:

- On April 24, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the AmerisourceBergen Orlando, Florida Distribution Center ("Orlando Facility") alleging failure to maintain effective controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement which resulted in the suspension of its DEA registration;

- On November 28, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Auburn, Washington Distribution Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydrocodone;

- On December 5, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone;

- On December 7, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Swedesboro, New Jersey Distribution Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydrocodone;

- On January 30, 2008, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Stafford, Texas Distribution Center (Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone;

- On May 2, 2008, McKesson Corporation entered into an *Administrative Memorandum of Agreement* ("2008 MOA") with the DEA which provided that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform the DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program;"

- On September 30, 2008, Cardinal Health entered into a *Settlement and Release Agreement and Administrative Memorandum of Agreement* with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the

---

I8xNEWGPoFYJ:https://oig.justice.gov/reports/2014/e1403.pdf+&cd=1&hl=en&ct=clnk&gl=us

diversion of controlled substances at its distribution facilities located in McDonough, Georgia; Valencia, California; and Denver, Colorado;

- On February 2, 2012, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against Cardinal Health Lakeland, Florida Distribution Center for failure to maintain effective controls against diversion of oxycodone;

- On December 23, 2016, Cardinal Health agreed to pay a $44 million dollar fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center; and

- On January 5, 2017, McKesson Corporation entered into an *Administrative Memorandum Agreement* with the DEA wherein it agreed to pay a $150,000,000 civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora, CO, Aurora, IL, Delran, NJ, LaCrosse, WI, Lakeland, FL, Landover, MD, La Vista NE, Livonia, MI, Metheun, MA, Santa Fe Springs, CA, Washington Courthouse, OH and West Sacramento, CA.

71. Rather than abide by their explicit duties under public safety laws and regulations, the Defendant Wholesale Distributors, individually and collectively through trade groups in the industry, pressured the U.S. Dept. Of Justice to halt prosecutions and lobbied Congress to strip the DEA of its ability to immediately suspend distributor registrations. The result was a "sharp drop in enforcement actions" and the passage of the "Ensuring Patient Access and Effective Drug Enforcement Act" which, ironically, raised the burden for the DEA to revoke a distributor's license from "imminent harm" to "immediate harm" and provided the industry the right to "cure" any violations of law before a suspension order can be issued.[38]

---

[38] *See*, Lenny Bernstein and Scott Higham, *Investigation: The DEA slowed enforcement while the opioid epidemic grew out of control,* THE WASHINGTON POST (October 22, 2016); Lenny Bernstein and Scott Higham, *Investigation: U.S. senator calls for investigation of DEA enforcement slowdown amid opioid crisis,* THE WASHINGTON POST (March 6, 2017); Eric Eyre, *DEA agent: 'We had no leadership' in WV amid flood of pain pills,* Charleston Gazette (February 18, 2017).

72. Meanwhile, the opioid epidemic continues to rage unabated in the Nation, the State and Dillon County.

73. The epidemic still rages because the fines and suspensions imposed by the DEA do not change the conduct of the Defendant Wholesale Distributors. They pay fines as a cost of doing business in an industry which generates billions of dollars in annual revenue. They hold multiple DEA registration numbers and when one facility is suspended, they simply ship from another facility. As bluntly noted by Cardinal Health in its filings in *Cardinal Health, Inc. v. Holder*, 864 F. Supp. 2 203 (D.D.C. 2012), "suspension . . . will not address the harm DEA alleges because it will not prevent pharmacies filling illegitimate prescriptions from simply obtaining controlled substances from another distributor.[39]

74. Defendant Wholesale Distributors' repeated shipments of suspicious orders, over an extended period of time, in violation of public safety laws and regulations, and without reporting the suspicious orders to the relevant authorities - including the DEA, the S.C. Bureau of Drug Control, and/or Board of Pharmacy – was wanton, willful, and in conscious disregard for the rights and safety of a large segment of the U.S. population impacted directly and indirectly by the opioid epidemic.

75. The unlawful conduct by the Defendant Wholesale Distributors was purposeful and intentional. They refused, and continue to refuse, to abide by the duties imposed by law, even though compliance is required to maintain a South Carolina license/registration to distribute prescription opioids and to maintain their DEA registration.

---

[39] Memorandum of Points of Authorities in Support of Cardinal Health's Motion for Temporary Restraining Order (Doc. 3-1), at p. 22, *Cardinal Health, Inc. v. Holder,* No. 1:12-cv-00185-RBW (D.C. Cir. Feb. 3, 2012).

76. Defendant Wholesale Distributors have publicly disavowed any duty beyond reporting suspicious orders and, even then, have claimed they are not required to report all suspicious orders. In *Masters Pharmaceuticals, Inc. v. U.S. Drug Enforcement Admin.*, 2016 WL 1321983 (D.C. Cir. April 4, 2016), the HDA and the National Association of Chain Drug Stores submitted amicus briefs regarding the legal duties of wholesale distributors in which they inaccurately argued that:

- Nothing "requires distributors to investigate the legitimacy of orders, or to halt shipment of any orders deemed to be suspicious." (*Id*. at *14);
- "DEA's regulations [] sensibly impose[] a duty on distributors simply to report suspicious orders, but left it to DEA and its agents to investigate and halt suspicious orders." (*Id.* at ** 24-25);
- "DEA now appears to have changed its position to require that distributors not only report suspicious orders but investigate and halt suspicious orders. Such a change in agency position must be accompanied by an acknowledgment of the change and a reasoned explanation for it. In other words, an agency must display awareness that it is changing position and show that there are good reasons for the new policy. This is especially important here, because imposing intrusive obligations on distributors threatens to disrupt patient access to needed prescription medications." (Internal citations and quotes omitted) (*Id*. at *14); and
- "Imposing a duty on distributors – which lack the patient information and the necessary medical expertise – to investigate and halt orders may force distributors to take a shot-in-the-dark approach to complying with the DEA's demands." (*Id.* at *26).

77. The positions taken by the trade groups is emblematic of the position taken by the Defendant Wholesale Distributors in a futile attempt to deny their legal obligations to prevent diversion of the dangerous drugs while continuing their gravy train of mega-profits unabated.[40]

[40] *See* Amicus Curiae Brief of HDMA, *Cardinal Health, Inc. v. United States Dept. Justice,* 2012 WL 1637016, at *3 (arguing the wholesale distributor industry "does not know the rules of the road," because they claim (inaccurately) that "DEA has not adequately explained

78. The Court of Appeals for the District of Columbia recently issued its opinion affirming that a wholesale drug distributor does, in fact, have a duty to report all suspicious orders and also has duties beyond reporting. *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, No. 15-01355 (D.C. Cir. June 30, 2017). The Circuit Court upheld the revocation of Masters Pharmaceutical's license and determined that DEA regulations require that in addition to reporting suspicious orders, distributors "must ... decline to ship the order, or conduct some 'due diligence' and – if it is able to determine that the order is not likely to be diverted into illegal channels – ship the order." *Id*., Slip Op. at 5. Masters Pharmaceutical was in violation of legal requirements not only because it failed to report suspicious orders, but also because it failed to conduct necessary investigations and continued to fill suspicious orders. *Id*., at 14-17, 24. Before a distributor may ship a suspicious order, a distributor's investigation must dispel all red flags giving rise to suspicious circumstances. *Id*. at 24. The Circuit Court also rejected any argument that the DEA, by its ruling, was creating or imposing new duties on distributors. *Id*., at 18-21.

79. Wholesale Distributor McKesson has specifically admitted that it breached its duties to monitor, report, and prevent suspicious orders. Pursuant to an Administrative Memorandum of Agreement ("2017 Agreement") entered into between McKesson and the DEA in January 2017, McKesson admitted that, at various times during the period from January 1, 2009, through the effective date of the Agreement (January 17, 2017), it "did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected

---

them").

by McKesson as suspicious based on the guidance contained in the DEA Letters about the requirements set forth in 21 C.F.R. §1301.74(b) and 21 U.S.C.A. § 842(a)(5)."[41] Further, the 2017 Agreement specifically finds that McKesson "distributed controlled substances to pharmacies even though those McKesson distribution centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by C.F.R. § 1305.04(a).[42] McKesson admitted that, during this period, it "failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA's implementing regulations, 21 C.F.R. Part 1300 *et seq*., at the McKesson Distribution Centers."[43] Due to these violations, McKesson agreed that its authority to distribute controlled substances from certain facilities would be partially suspended.[44]

80. The 2017 McKesson Memorandum of Agreement followed a 2008 Settlement Agreement in which McKesson also admitted failure to report suspicious orders of controlled

---

[41] *See* Administrative Memorandum of Agreement between the United States Department of Justice, the Drug Enforcement Agency, and McKesson Corporation (effective date January 17, 2017). A copy is attached as Exhibit 9 hereto.

[42] *Id.* at 4.

[43] *Id.*

[44] *Id.* at 6.

substances to the DEA.[45] In the 2008 Settlement Agreement, McKesson "recognized that it had a duty to monitor its sales of all controlled substances and report suspicious orders to DEA," but had failed to do so.[46] The 2017 Memorandum of Agreement documents that McKesson continued to breach its admitted duties by "fail[ing] to properly monitor its sales of controlled substances and/or report suspicious orders to DEA, in accordance with McKesson's obligations under the 2008 Agreements, the Act, and 21 C.F.R. §1301.74(b)."[47] The 2017 Memorandum of Agreement and the associated Settlement Agreement and Release revealed to the public that McKesson was not complying with the 2008 Settlement Agreement. As a result of these violations, McKesson was fined and required to pay the United States $150,000,000.[48]

C. The Opioid Plague in South Carolina Was Caused By, and Is the Proximate Result Of, Defendants' Breaches of Mandatory Duties to Maintain Effective Controls to Prevent the Diversion of Dangerous, Highly Addictive Opioids.

81. Defendant Wholesale Distributors' failure to monitor, investigate, refuse to fill and report suspicious orders is a direct and proximate cause of the diversion of millions of doses of prescription opioids into the illicit market for illegitimate and/or non-medical purposes, the

---

[45] *Id*. at 4.

[46] *Id.*

[47] *Id.* at 4. *See also*, Settlement Agreement and Release between the United States of America (acting through the Department of Justice and on behalf of the Drug Enforcement Administration) and McKesson Corporation, effective date January 17, 2017) ("2017 Settlement Agreement and Release") ("McKesson acknowledges that, at various times during the Covered Time Period [2009-2017], it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious "in a manner fully consistent with the requirements set forth in the 2008 MOA." A copy of the Settlement Agreement and Release is attached hereto as Exhibit 10.

[48] *Id.* at 6

very harm the federal and South Carolina statutes and regulations were intended to prevent.

82. The unlawful diversion of prescription opioids directly and proximately caused at least in substantial part, the opioid epidemic plaguing South Carolina, and specifically Dillon County, resulting in widespread morbidity and mortality. The unlawful diversion of prescription opioids directly and proximately caused, at least in part, the heroin epidemic currently plaguing South Carolina, and specifically Dillon County.

D. Dillon County and the Public Welfare of its Citizens Have Been Damaged by Defendants' Participation in the Unlawful Diversion of Dangerous, Highly Addictive Opioids.

1. Opioid-related addiction and death has reached epidemic proportion.

83. The number of annual opioid prescriptions written in the United States is now roughly that of the number of adults in the population.[49]

84. Many Americans are now addicted to prescription opioids, and the number of deaths due to prescription opioid overdose is a national tragedy.[50]

85. Among 47,055 drug overdose deaths that occurred in 2014 in the United States, 28,647 (60.9%) involved an opioid.[51]

2. While the opioid epidemic is a national tragedy, the statistics are particularly tragic in South Carolina and Dillon County.

86. South Carolina has been devastated by the opioid epidemic.

---

[49] *See* Robert M. Califf, M.D., et al., *A Proactive Response to Prescription Opioid Abuse*, NEW ENGL. J. MED., 374;1480 (April 14, 2016).

[50] *Id.*

[51] 48 *See* Rose A. Rudd, MSPH, et al., *Increases in Drug and Opioid-Involved Overdose Deaths - United States, 2010-2015, Morbidity and Mortality Weekly Report (MMWR)*, Centers for Disease Control and Prevention, 65(50-51); 1445-1452 (December 30, 2016).

87. The overdose mortality rates in South Carolina have increased sharply in recent years. From 2015 to 2016 alone, South Carolina saw a 15.3 percent increase in overdose fatalities.[52] In 2016, there were 879 South Carolina overdose deaths, up from 761 South Carolina overdose deaths in 2015.[53]

88. Opioid addiction is now the primary reason that South Carolinians seek substance abuse treatment.

3. General declaration of damages applicable to all Causes of Action herein.

89. Prescription opioid abuse, addiction, morbidity, and mortality are hazards to the public health and safety in Dillon County, South Carolina. The Defendant Wholesale Distributors' actions are a serious breach of the public trust which has resulted in overdose deaths, and untold expenses and lost revenue for Dillon County. Each Defendant played a significant role in creating what amounts to a pervasive public nuisance plaguing the community, which nuisance remains unabated.

90. These dangerous and addictive drugs were and are diverted, misused, and abused, to the point where citizens of South Carolina, including the residents of Dillon County, have lost their jobs, health and even their lives. Cities, towns and counties, like Dillon County, are left in the wake of this malfeasance to clean up the mess and try to restore order.

91. Overdose deaths are only one consequence of the opioid addiction epidemic. The damages to Dillon County, South Carolina include, without limitation, costs sustained by the

---

[52] Centers for Disease Control and Prevention, Drug Overdose Death Data at https://www.cdc.gov/drugoverdose/data/statedeaths.html.

[53] *Id.*

County for law enforcement, emergency response, public safety services, and other expenses relating to the opioid epidemic.

92. When the dangerous and addictive drugs cause harm to the public health of Dillon County residents, in the form of addiction, overdose and death, it falls to the County to dispatch emergency services and law enforcement personnel, investigate crimes, overdoses and deaths, transport suspects to regional jail facilities, organize and maintain drug courts, and man public health clinics.

93. Opioid addition and misuse results in an increase in emergency room visits, emergency responses, and emergency medical technicians' administration of naloxone – the antidote to opioid overdose. In South Carolina, administration of naloxone (or Narcan) rose from 4,187 doses in 2015 to 6,427 doses in 2016.

94. As the dangerous and addictive drugs cause harm to the neighborhoods, schools, businesses, public utilities of Dillon County in the form of litter, blight, damaged and destroyed public property, among other things, the County has had to step in to enforce codes, clean up streets and neighborhoods, and repair and/or replace damaged and destroyed public property.

95. The number of criminal possession charges for opioid drugs has increased. In addition, the dangerous and addictive drugs have caused increases in other crimes, including crimes related to illegal use of street drugs like heroin and methamphetamines, forcing Dillon County to dispatch police, prosecute cases, and transport suspects to regional jail facilities. This has placed increased budgetary burdens on the County for law enforcement, emergency response services and public safety.

96. Infants have not been immune to the impact of opioid abuse. There has been a

dramatic rise in the number of infants who are born addicted to opioids due to prenatal exposure and suffer from neonatal abstinence syndrome ("NAS," also known as neonatal opioid withdrawal syndrome, or "NOWS"). These infants painfully withdraw from the drug once they are born, cry nonstop from the pain and stress of withdrawal, experience convulsions or tremors, have difficulty sleeping and feeding, and suffer from diarrhea, vomiting and low weight gain, among other serious symptoms. The long-term developmental effects are still unknown, though research in other states indicates that these children are likely to suffer from continued, serious neurologic and cognitive impacts, including hyperactivity, attention deficit disorder, lack of impulse control and a higher risk of future addiction. In South Carolina, the incidence of NAS has quadrupled between 2000 and 2013 from roughly 1 infant per 1000 hospital births to 4 per 1000, which would amount to 221 infants in 2013. These unfortunate babies require County resources for care, support and special education. Funds for their special needs must be earmarked to extend far into the future.

97. Children have not escaped the opioid epidemic unscathed. The number of South Carolina children removed from homes with substance abuse nearly doubled from 397 in the year ending July 2011 to 641 in the year ending July 2016. In addition, easy access to prescription opioids has made opioids a recreational drug of choice among South Carolina teenagers.

98. Employers have lost the value of productive and healthy employees. Dillon County has lost tax revenue and incurred both direct and indirect costs as a result of workplace accidents, absenteeism, and decreased productivity from prescription and illegal drug abuse caused in whole or in part by Defendant Wholesale Distributors' actions.

99. To eliminate the hazard to public health and safety, and abate the public nuisance,

a "multifaceted, collaborative public health and law enforcement approach is urgently needed."[54]

100. A comprehensive response to this crisis must focus on preventing new cases of opioid addiction, identifying early opioid-addicted individuals, and ensuring access to effective opioid addiction treatment while safely meeting the needs of patients experiencing pain.[55]

101. Plaintiff seeks economic damages from the Defendant Wholesale Distributors as reimbursement for the costs associated with past efforts to address and ameliorate these hazards to public health and safety.

102. Plaintiff further seeks economic damages from the Defendant Wholesale Distributors to pay for the damages incurred and the future costs required to permanently eliminate the hazards to public health and safety and abate the temporary public nuisance.

103. Defendants acted negligently, recklessly, willfully, wantonly, and with a conscious disregard for the rights and safety of other persons and Plaintiff seeks punitive damages to deter the Defendant Wholesale Distributors and others from committing like offenses in the future.

IV. CAUSES OF ACTION.

COUNT I
FOR A FIRST CAUSE OF ACTION
(UNFAIR TRADE PRACTICES § 39-5-10 *ET SEQ., S.C. CODE ANN.*)

104. Plaintiff realleges and reiterates all of the allegations contained in paragraphs 1

---

[54] *Id.*

[55] *See* Alexander GC, Frattaroli S, Gielen AC, eds. *The Prescription Opioid Epidemic: An Evidence-Based Approach*, Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland: 2015, available at http://www.jhsph.edu/research/centers-and-institutes/center-for-drug-safety-and-effectiveness/opioid-epidemic-town-hall-2015/2015-prescription-opioid-epidemic-report.pdf.

through 103 as fully as if repeated herein verbatim.

105. The South Carolina Unfair Trade Practices Act ["SCUTPA"] was modeled after the Federal Trade Commission Act, which provides "[u]nfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices affecting commerce, are hereby declared unlawful." 15 U.S.C. § 45(a)(1). SCUTPA "declares unfair or deceptive acts or practices in trade or commerce unlawful." *Singleton v. Stokes Motors, Inc.*, 358 S.C. 369, 379, 595 S.E.2d 461, 466 (2004) (citing *S.C. Code Ann.* § 39-5-20(a) (2002)).

106. The terms "unfair" and "deceptive" are not defined in SCUTPA; rather, in § 39-5-20(b) of the Act, the legislature directs that in construing those terms, the courts of our state "will be guided by" decisions from the federal courts, the Federal Trade Commission Act (FTCA), and interpretations given by the Federal Trade Commission (FTC).

107. "An unfair trade practice has been defined as a practice which is offensive to public policy or which is immoral, unethical, or oppressive." *deBondt v. Carlton Motorcars, Inc.*, 342 S.C. 254, 269, 536 S.E.2d 399, 407 (Ct.App. 2000) (citing *Young v. Century Lincoln–Mercury, Inc.*, 302 S.C. 320, 326, 396 S.E.2d 105, 108 (Ct.App.1989), *aff'd in part, rev'd in part on other grounds*, 309 S.C. 263, 422 S.E.2d 103 (1992)).

108. The practices of the Defendant Wholesale Distributors described herein are patently "offensive to public policy" and manifestly "immoral, unethical, or oppressive." Accordingly, Defendants' practices are and continue to be unfair trade practices within the contemplation of the SCUTPA.

109. The unfair trade practices of these Defendants proximately caused and continue to cause an ascertainable loss of money and property to be sustained by the Plaintiff Dillon County.

110. The health and safety of the citizens of Dillon County, including those who have abused or will abuse prescription opioids, or were led by their addiction to use and abuse illegal drugs, is a matter of great public interest and of legitimate concern to Dillon County and its citizens. The practices of the Defendant Wholesale Distributors described herein have adversely affected and continue to adversely affect the public interest of the Dillon County community and have the potential for repetition until such time as Defendants are held accountable.

111. The Plaintiff is informed and believes that Defendant Wholesale Distributors employed the unfair trade practices detailed herein willfully and in knowing violation of § 39-5-20 *S.C. Code Ann.*

112. Plaintiff is informed and believes that it is entitled to an award of actual damages as detailed hereinabove at paragraphs 89 through 103, in an amount to be determined by the jury, treble actual damages, and such other relief as the Court deems necessary or proper.

113. Plaintiff is informed and believes that it is entitled to an award of reasonable attorney's fees and costs.

COUNT II
FOR A SECOND CAUSE OF ACTION
(NUISANCE)

114. Plaintiff realleges and reiterates all of the allegations contained in paragraphs 1 through 113 as fully as if repeated herein verbatim.

115. Defendant Wholesale Distributors, individually and acting through their employees and agents, have created and continue to perpetuate and maintain a public nuisance in Dillon County through the massive distribution of millions of doses of highly addictive, commonly abused prescription opioids.

116. Defendants Wholesale Distributors' failure to put in place effective controls and procedures to guard against theft and diversion of controlled substances, their failure to adequately design and operate systems to disclose suspicious orders of controlled substances, and their failure to properly and timely inform the State of South Carolina and/or the DEA of suspicious orders when suspected or discovered, has created a public nuisance in Dillon County.

117. Defendants Wholesale Distributors have enabled and/or failed to prevent the illegal diversion of opioids into the black market, including through drug rings, pill mills, and other dealers in Dillon County, with actual knowledge, intent, and/or reckless or negligent disregard that such pills would be illegally trafficked and abused.

118. Defendants Wholesale Distributors were on notice that an epidemic from prescription drug abuse existed and has existed during all relevant times for this Complaint as the result of:

- Extensive media coverage of prescription drug abuse and its consequences by both national and local print, television, and radio media;
- Publications disseminated from government sources, as well as warnings and recommendations contained in trade and professional journals;
- Changes in law and regulations designed specifically to address the growing problem of prescription drug abuse;
- Widespread publication of articles and treatises containing extensive references and statistics concerning national, state and local crisis level problems resulting from prescription drug abuse, including, but not limited to, rising death rates from prescription drug overdose; and
- Filings in enforcement actions by the DEA.

119. Notwithstanding the knowledge of this epidemic of prescription drug abuse and related addiction nationwide and in South Carolina, including Dillon County, Defendant

Wholesale Distributors have persisted in a pattern and practice of distributing or dispensing controlled substances which were well-known to be abused and diverted in such quantities and with such frequency that the Defendant Wholesale Distributors knew or should have known that these substances were not being prescribed and consumed for legitimate medical purposes.

120. Defendants Wholesale Distributors knew or should have known their conduct would cause harm or inconvenience to Dillon County in a multitude of ways.

121. Defendants Wholesale Distributors' conduct annoys, injures, and/or endangers the comfort, repose, health, and safety of others and has caused and continues to cause harm to Dillon County and its residents.

122. As such, Defendants' wrongful conduct has given rise to a public nuisance, including unlawful availability, abuse of opioids, and the proliferation of addiction to legal and illegal substances within Dillon County.

123. As a direct and proximate result of the conduct of the Defendants, as set forth herein, Defendants have negligently and/or unreasonably interfered with the rights of Dillon County citizens to be free from unwarranted injuries, addictions, diseases, sicknesses, overdoses, criminal actions, and have caused ongoing damage, harm, and inconvenience to the community and its residents who have been exposed to the risk of addiction to prescription drugs, who have become addicted, and/or have suffered other adverse consequences from the use of the addictive prescriptions drugs, and have been adversely affected by the addiction and abuse of others in their communities from the highly addictive, prescription pain medication distributed by Defendants.

124. Stemming the flow of illegally distributed prescription opioids, and abating the

nuisance caused by the illegal flow of opioids, will help alleviate this problem, save lives, prevent injuries and make Dillon County a safer place to live. Plaintiff is informed and believes that Dillon County has a clear and ascertainable right to abate the conduct that perpetuates this continuing public nuisance.

125. Defendants Wholesale Distributors' conduct is a direct and proximate cause of deaths and injuries to Dillon County residents, to costs borne by Dillon County, and a significant and unreasonable interference with public health, safety and welfare, and with the public's right to be free from disturbance and reasonable apprehension of danger to person and property. The Plaintiff is informed and believes that it is entitled to an award of actual damages to recover for its own harm suffered, including, but not limited to expenses for police, emergency, health, prosecution, corrections and other services as hereinabove enumerated at paragraphs 89 through 103.

126. Plaintiff is informed and believes that it is entitled to all legal and equitable relief allowed by law, including compensatory damages, and punitive damages from Defendant Wholesale Distributors for the creations and continuation of a public nuisance. Plaintiff is further informed and believes it is entitled to reasonable costs of abatement, including but not limited to funding for treatment programs.

COUNT III
FOR A THIRD CAUSE OF ACTION
(NEGLIGENCE)

127. Plaintiff realleges and reiterates all of the allegations contained in paragraphs 1 through 126 as fully as if repeated herein verbatim.

128. Defendant Wholesale Distributors are distributors of controlled substances, and

registrants subject to oversight by the DEA, S.C. Bureau of Drug Control and the S.C. Board of Pharmacy. Defendant Wholesale Distributors must comply with the laws and regulations of South Carolina, as well as with industry customs and standards developed in large part by these particular Defendant Wholesale Distributors.

129. Industry standards require numerous actions on the part of each Wholesale Distributor to protect the health and welfare of those impacted by distribution of dangerous and addictive opioids, including but not limited to:

- know its customers;
- know its customer base;
- know the population base served by a particular pharmacy or drug store;
- know the average prescriptions filled each day;
- know the percentage of diverted and/or abused controlled substances distributed as compared to overall purchases;
- have a description of how the dispenser fulfills its responsibility to ensure that prescriptions filled are for legitimate medical purposes; and
- be able to identify the physicians and bogus pain clinics and centers for the alleged treatment of pain that are the pharmacy or drug stores' most frequent prescribers.

130. As licensed registrants, Defendant Wholesale Distributors were required to design and maintain effective controls to identify suspicious orders, to monitor for suspicious orders, to investigate suspicious orders, to refuse to ship suspicious orders, and to report suspicious orders, in compliance with state and federal laws and regulations, in furtherance of the public health, welfare and safety, as detailed above.

131. Instead, Defendant Wholesale Distributors negligently turned a blind eye in order

to continue distributing large quantities of commonly-abused, highly addictive, opioids to clients who were serving a customer base comprised of individuals who were abusing prescription medications, many of whom were addicted or who reasonably could be expected to become addicted or to engage in illicit drug transactions.

132. Defendant Wholesale Distributors took no action, or insufficient action to stem the flow of opioids into the hands of abusers, misusers, and diverters into Dillon County.

133. Accordingly, Defendant Wholesale Distributors were negligent, willful, wanton, reckless and grossly negligent in their failure to comply with and conform their conduct to industry standards and to the mandates of federal and state laws and regulations. Defendant Wholesale Distributors' conduct was negligence *per se*.

134. As a direct and proximate result of Defendant Wholesale Distributors' negligence, recklessness, willfulness, wantonness and gross negligence, as aforesaid, Plaintiff has suffered and will continue to suffer devastating consequences as a result of the Defendant Wholesale Distributors' actions. As detailed more fully above at paragraphs 89 through 103, the economic damages incurred by Plaintiff include, but are not limited to, money expended on law enforcement, prosecutions, emergency response services, public utilities, nuisance abatement, property damage repair, lost tax revenues, code enforcement, and responding to the tragedy of infants born to drug addicted mothers.

COUNT IV
FOR A FOURTH CAUSE OF ACTION
(UNJUST ENRICHMENT)

135. Plaintiff realleges and reiterates all of the allegations contained in paragraphs 1 through 134 as fully as if repeated herein verbatim.

136. Collectively, Defendant Wholesale Distributors accrued tremendous profits while fueling the prescription drug epidemic in South Carolina, including Dillon County, to the extreme detriment and expense of the County.

137. Defendant Wholesale Distributors continue to receive these exorbitant profits from the distribution of opioids in Dillon County.

138. Defendant Wholesale Distributors were each unjustly enriched by their negligent, intentional, malicious, oppressive, illegal, immoral and unethical acts, omissions, and wrongdoing to the injury and expense of Plaintiff.

139. Defendant Wholesale Distributors' negligent, intentional, malicious, oppressive, illegal, immoral and unethical acts, omissions, and wrongdoing are directly related to the damages and losses, and were to the detriment of the Plaintiff. As a result of all Defendant Distributors' actions, omissions and wrongdoing, Plaintiff has expended substantial amounts of money that it would not have otherwise expended on numerous services, including, but not limited to: law enforcement, prosecutions, emergency response services, public utilities, nuisance abatement, property damage repair, and code enforcement.

140. Defendant Wholesale Distributors are liable to Plaintiff for damages incurred as a result of Defendant Distributors' negligent, intentional, malicious, oppressive, illegal and unethical acts, omissions, and wrongdoing contained herein.

141. Plaintiff's payment for these damages on Defendant Wholesale Distributors' behalf conferred beneficial services on Defendants; satisfied a debt or duty owed by Defendants; and/or saved Defendants' expense or loss.

142. Defendant Wholesale Distributors' negligent, intentional, malicious, oppressive,

illegal, immoral and unethical acts, omissions, and wrongdoing entitle Plaintiff to disgorgement of the profits received by Defendants for all sales it made in Dillon County, South Carolina or to Dillon County residents from 2007 to present.

WHEREFORE, Plaintiff prays for judgment against Defendant Wholesale Distributors, as following:

A. For an award of actual and compensatory damages pursuant to the First, Second, and Third Causes of Action in an amount to be determined by the jury at the trial of this action;

B. For an award trebling the actual and compensatory damages pursuant to the First Cause of Action;

C. For an award of reasonable attorneys fees pursuant to the First Cause of Action;

D. For an award of punitive damages pursuant to the Second and Third Causes of Action in an amount to be determined by the jury at the trial of this action;

E. For an award of reasonable costs and injunctive relief in furtherance of abatement of the public nuisance created by Defendant Wholesale Distributors pursuant to the Second Cause of Action;

F. For disgorgement of profits pursuant to the Fourth Cause of Action;

G. For pre and post judgment interest;

H. For the costs and disbursements of this action; and

I. For such other and further relief as this Honorable Court may deem just and proper.

[SIGNATURES ON FOLLOWING PAGE]

Respectfully submitted,

s/Charles W. Whetstone, Jr.
Charles W. Whetstone, Jr., Fed. ID #4604
James E. Brogdon, III, Fed. I.D. #10872
Cheryl F. Perkins, Fed. ID # 4969
John Eric Fulda, Fed. ID #7328
WHETSTONE, PERKINS & FULDA, LLC
Post Office Box 8086
601 Devine Street (29201)
Columbia, South Carolina 29202
cperkins@attorneyssc.com
jfulda@attorneyssc.com
cwhetstone@attorneyssc.com
Phone (803) 799-9400
Facsimile (803)799-2017

Annesley H. DeGaris
Alabama State Bar #ASB9182-A63A
DeGaris & Rogers, LLC
Two North Twentieth Street
Suite 1030
Birmingham, Alabama 35203
Phone: (205) 558-9000
www.degarislaw.com
To Seek Pro Hac Vice

ATTORNEYS FOR PLAINTIFF

Columbia, South Carolina
February 8, 2018